

Remarks

I. Support for Amendments

Support for the foregoing amendments to the claims can be found throughout the specification as originally filed. Support for claims 31-34 can be found, for example, at page 12, lines 26-28; page 12, lines 15-17; page 16, line 17 through page 19, line 27; and page 57, line 25 through page 58, line 10. Support for claims 35-37 can be found at page 11, lines 24-26 and page 46, lines 16-30. Support for claim 38 can be found at page 65, lines 18-19. Support for claim 39 can be found at page 47, lines 3-6 and Example 5. Support for claims 40 and 41 can be found at page 19, lines 30-31 and page 19, line 30 through page 20, line 18. Support for claims 42 and 43 can be found at page 25, line 16 through page 27, line 32. Support for claims 44-47 can be found at page 12, lines 26-28; page 12, lines 15-17; page 16, line 17 through page 19, line 27; and page 57, line 25 through page 58, line 10. Support for claims 48-50 can be found at page 11, lines 24-26 and page 46, lines 16-30. Support for claim 51 can be found at page 65, lines 18-19. Support for claim 52 can be found at page 47, lines 3-6 and Example 5. Support for claims 53 and 54 can be found at page 19, lines 30-31 and page 19, line 30 through page 20, line 18. Support for claims 55 and 56 can be found at page 25, line 16 through page 27, line 32. Support for claim 57 can be found at page 12, lines 26-28; page 12, lines 15-17; page 16, line 17 through page 19, line 27; and page 57, line 25 through page 58, line 10 and page 4, lines 24-25. Support for claims 58-60 can be found at page 11, lines 24-26 and page 46, lines 16-30. Support for claim 61 can be found at page 65, lines 18-19. Support for claim 62 can be found at page 47, lines 3-6 and Example 5. Support for claims 63 and 74 can be found at page 19, lines 30-31 and page 19, line 30 through page

20, line 18. Support for claims 65 and 66 can be found at page 25, line 16 through page 27, line 32. Accordingly, these amendments add no new matter to the application. Entry and consideration of the amendments are respectfully requested.

II. Status of the Claims

Reconsideration of this application is respectfully requested.

By the foregoing amendments, claims 1-4 and 6-30 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein.¹ New claims 31-66 are sought to be added. Upon entry of these amendments, claims 5 and 31-66 are pending in the application, with claims 5, 31, 44, and 57 being the independent claims.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

III. Summary of the Office Action

In the Office Action dated September 29, 2005, the Examiner has made one objection to the claims and four rejections of the claims. Applicants respectfully offer the following remarks concerning each of these elements of the Office Action.

IV. Restriction Requirement

In the Office Action dated September 29, 2005, the Examiner has made the restriction Requirement final. Accordingly, Applicants have canceled claims 11-21 and

¹ Applicants note that the "Summary" page of the September 29, 2005 Office Action states that claims 1-10 and 22 were pending, when in fact, claims 1-30 were pending prior to the amendment presented herein.

23-30. Applicants reserve the right to pursue the subject matter of these claims in related divisional applications.

V. Objection of claims 1-2, 5-10 and 22

At page 3 of the Office Action, claims 1-2, 5-10 and 22 have been objected to for allegedly encompassing non-elected subject matter. As indicated above, claims 1-2, 6-10 and 22 have been cancelled without prejudice or disclaimer and claim 5 has been withdrawn. Hence, this objection has been rendered moot.

VI. The Rejection under 35 U.S.C. § 101 is Traversed.

At pages 3-6 of the Office Action, claims 1-4, 8-10 and 20 have been rejected under 35 U.S.C. § 101 for allegedly not being supported by either a specific and substantial asserted utility or a well established utility. Applicants respectfully traverse this rejection. As an initial note, Applicants respectfully assume that claim 20 referred to in this rejection should be claim 22. As indicated in section 1 at page 2 of the Office Action, claim 22, not claim 20, is under examination in this Office Action. If Applicant's assumption is not correct, Applicants respectfully request that the Examiner contact the undersigned at the number provided.

Applicant respectfully disagrees with this rejection. However, to expedite prosecution of the present application and not in acquiescence to this rejection, claims 1-4, 8-10 and 22 have been cancelled without prejudice or disclaimer, thus rendering moot this rejection. However, Applicant respectfully traverses this rejection, as it may be applied to the newly added claims.

A. The Examiner Has Failed to Establish That An Artisan of Ordinary Skill Would Reasonably Doubt All Asserted Utilities.

Applicants note that the manner of making and using an invention disclosed in a specification must be accepted by the PTO “unless there is reason to doubt the objective truth of the statements contained therein.” *In re Marzocchi*, 58 C.C.P.A. 1069, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971); *see also Utility Examination Guidelines*, 66 Fed. Reg. 1092, 1098-99 (Jan. 5, 2001) (“*Utility Guidelines*”). Instances in which an assertion of specific utility is not credible are rare. *See* MPEP § 2107 (7th ed. Rev. 1, Feb. 2000). Indeed, the Federal Circuit affirmed the standard for making a utility rejection that was set forth in *In re Brana*, 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995):

The PTO cannot make this type of rejection . . . unless it has reason to doubt the objective truth of the statements contained in the written description. *See Brana*, 51 F.3d at 1566, 34 USPQ2d at 1441.

In re Cortright, 49 U.S.P.Q.2d 1464, 1466 (Fed. Cir. 1999). The PTO’s own guidelines provide:

Any rejection based on lack of utility should include a detailed explanation why the claimed invention has no specific and substantial credible utility. Whenever possible, the examiner should provide documentary evidence . . . (e.g., scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents) to support the factual basis for the prima facie showing of no specific and substantial credible utility. If documentary evidence is not available, the examiner should specifically explain the scientific basis for his or her factual conclusions.

Utility Guidelines, 66 Fed. Reg. at 1098. Further, the Federal Circuit has recently articulated the standard for utility:

The threshold of utility is not high: An invention is “useful” under section 101 if it is capable of providing some identifiable benefit. See *Brenner v. Manson*, 383 U.S. 519, 534 (1996); *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992) (“To violate § 101 the claimed device must be totally incapable of achieving a useful result”); *Fuller v. Berger*, 120 F. 274, 275 (7th Cir. 1903) (test for utility is whether invention “is capable of serving any beneficial end”).

Juicy Whip, Inc. v. Orange Bang Inc., 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999).

The Examiner has not made the required showing that even one, much less all, of the disclosed utilities for Nogo receptor 2 (NgR2) polynucleotides would be unbelievable in light of the teachings of the specification. For example, the specification discloses that agents that interfere with the binding of NgR with its ligand improve axonal regeneration in clinical states in which axons have been damaged, including nerve damage as a result of trauma, infarction, and degenerative disorders of the central nervous system (CNS). See specification at page 3, lines 13-19. The specification further discloses that soluble NgR2 polypeptides can modulate the inhibition of axonal elongation by inhibiting the ligand of NgR from interacting with cell surface NgR. See specification at page 12, lines 15-30. In addition, the specification discloses that

[m]odulators of NgR activity will be therapeutically useful in treatment of diseases and physiological conditions in which normal or aberrant NgR activity is involved. NgR polynucleotides, polypeptides and modulators may be used in the treatment of diseases and conditions associated with demyelination. NgR polynucleotides and polypeptides, as well as NgR modulators, may also be used in diagnostic assays for such diseases and conditions.

See specification at page 76, lines 14-17. Furthermore, the specification discloses that NgR2 polypeptides could be used as therapeutics for treating a CNS disease, disorder, or injury including cerebral injury, spinal cord injury, stroke, demyelinating diseases, *e.g.*, multiple sclerosis, monophasic demyelination, encephalomyelitis, multifocal leukoencephalopathy, panencephalitis, Marchiafava-Bignami disease, Spongy degeneration, Alexander's disease, Canavan's disease, metachromatic leukodystrophy and Krabbe's disease. See specification at page 6, lines 7-18. Thus, the polynucleotides of the claims can be used for the diagnosis and treatment of diseases and conditions associated with aberrant or normal NgR activity by modulating the inhibition of axonal elongation. Therefore, the claimed polynucleotides certainly provide some identifiable benefit under *Juicy Whip*, and their utility is specific and substantial under the PTO's guidelines.

Thus, the Examiner has failed to provide any evidence or sound scientific reasoning to establish that an artisan would reasonably doubt all of the asserted utilities for the polynucleotides of the claims.

B. The Specification Discloses At Least One Specific Utility.

Applicants submit that the specification discloses a number of specific uses for NgR2 molecules. The Examiner stated that the "specification fails to provide objective evidence of any activity for the encoded protein or to show that this protein exists. . . . The specification does not disclose any disease or conditions known to be associated with or affected by the encoded polypeptide." See Office Action at page 4.

However, the specification states that NgR polynucleotides, polypeptides and modulators may be used in the treatment of diseases and physiological conditions in

which normal or aberrant NgR activity is involved. Additionally, the specification discloses specific diseases associated with aberrant or normal NgR activity including cerebral injury, spinal cord injury, stroke, multiple sclerosis, monophasic demyelination, encephalomyelitis, multifocal leukoencephalopathy, panencephalitis, Marchiafava-Bignami disease, Spongy degeneration, Alexander's disease, Canavan's disease, metachromatic leukodystrophy and Krabbe's disease. The use of NgR2 molecules to treat, for example, diseases and conditions associated with aberrant or normal NgR activity is a specific use that is not generally applicable to all proteins. (*See, e.g., Revised Interim Utility Guidelines Training Materials ("Utility Training Materials")* example 4, pages 32-33 (the use of an uncharacterized protein as an amino acid source or a protein supplement are uses that apply to "virtually every member of a general class of materials such as proteins" and therefore are not specific utilities under the facts of example 4.)). Thus, Applicants submit that the specification discloses at least one specific utility for NgR2.

C. At Least One Asserted, Specific Utility Is Substantial.

The Examiner stated that "[a]pplicant . . . does not identify or confirm a "real word" context of use." *See* Office Action at page 4. Applicants respectfully disagree.

Applicants respectfully emphasize that the specification discloses at least one specific and substantial utility for NgR2. A substantial utility is one that defines a "real world" use. (*Utility Training Materials* at page 6.) The use of NgR2 polynucleotides and polypeptides to treat, for example, diseases and conditions associated with aberrant or normal NgR activity are substantial utilities as they provide benefits to the public.

Thus, at least one asserted use for NgR2 is specific and substantial, as well as credible, as discussed further below.

Real-world value of an invention requires that “one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public.” *Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980). Furthermore, “any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a specific utility” (MPEP page 2107, column 2, lines 16-20). The specification and the claims provide support for the use of NgR2 polynucleotides for the diagnosis and treatment of diseases and conditions associated with aberrant or normal NgR activity (Specification at page 76, lines 14-17 and page 98, lines 9-25). Therefore, the use of NgR2 polynucleotides and polypeptides as a diagnostic and treatment for diseases and conditions associated with aberrant or normal NgR activity provides a public benefit and has real world value.

D. At Least One Asserted, Specific And Substantial Utility Is Credible.

Although the Examiner has failed to carry the burden of showing that the disclosed utilities are unbelievable, Applicants submit herewith documentary evidence that the noted utilities of NgR2 have been demonstrated in the art.

The Federal Circuit has set forth the standard by which an asserted utility is established through supporting data. The Federal Circuit pointed out that its “predecessor court has noted that adequate proof of any pharmacological activity constitutes a showing of practical utility.” *Cross v. Izuka*, 753 F.2d 1040, 224 U.S.P.Q. 739 (Fed. Cir. 1985), *citing Nelson v. Bowler*, 626 F.2d 853, 206 USPQ 881 (C.C.P.A.

1980) and *Rey-Bellet v. Englehardt* 493 F.2d 1380, 181 U.S.P.Q. 453 (C.C.P.A. 1974).

Specifically, the Federal Circuit held:

[B]ased upon the relevant evidence as a whole, there is a reasonable correlation between the disclosed *in vitro* utility and an *in vivo* activity, and therefore a rigorous correlation is not necessary where the disclosure of a pharmacological activity is reasonably based upon the probative evidence.

Cross v. Izuka, 753 F.3d at 1050.

Furthermore, utility can exist for therapeutic inventions “despite the fact that an applicant is at a very early stage in the development of a pharmaceutical product or therapeutic regimen based on a claimed pharmacological or bioactive compound or composition.” MPEP § 2107 (III) at 2100-27. “Usefulness in patent law . . . necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans.” *In re Brana*, 51 F.3d at 1568.

There is clearly a direct nexus between NgR2 and its use as a diagnostic and treatment for diseases and conditions associated with aberrant or normal NgR activity. The Examiner's attention is respectfully drawn to the Applicants' post-filing data, submitted herewith as Exhibits 1 and 2, that clearly shows that NgR2 binds myelin-associated glycoprotein (MAG), a natural ligand of NgR and promotes neurite outgrowth and axonal elongation. Applicants respectfully assert that these data further supports a function of the claimed fragments of NgR2 that is described in the specification, *i.e.*, that the claimed fragments of NgR2 bind MAG, a ligand of NgR thereby modulating the inhibition of axonal elongation by inhibiting the ligand of NgR from interacting with cell surface NgR. *See* attached Exhibits 1 and 2. Thus, NgR2 can be used as a diagnostic

and treatment for diseases and conditions associated with aberrant or normal NgR activity by modulating the inhibition of axonal elongation.

These post-filing data confirm the credibility of using NgR2 as a diagnostic and treatment for diseases and conditions associated with aberrant or normal NgR activity by promoting axonal regeneration and elongation. Therefore, the documentary evidence cited above confirms the credibility, as well as the specificity and substantiality, of at least one asserted utility for NgR2 of the present application.

In view of the facts set out above, Applicants submit that a skilled artisan would not reasonably doubt that the claimed polynucleotides can be useful in making NgR proteins or diagnosing and/or treating conditions involving aberrant or normal NgR activity. As such, Applicants assert that the presently claimed invention possesses a credible, specific and substantial utility that constitutes a patentable utility under 35 U.S.C. § 101. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 101 be reconsidered and withdrawn.

VII. The Rejections under 35 U.S.C. § 112, First Paragraph are Traversed

A. The Rejection of Claims 1-4, 8-10 and 20 for Enablement

At page 6 of the Office Action, claims 1-4, 8-10 and 20 have been rejected under 35 U.S.C. § 112, first paragraph for alleged lack of enablement for the reasons set forth under the utility rejection. As indicated above, Applicants are under the assumption that claim 22, not claim 20, has been rejected for enablement. In addition, as indicated above, claims 1-4, 8-10 and 22 have been cancelled without prejudice or disclaimer, thus

rendering moot this rejection. However, Applicant respectfully traverses this rejection, as it may be applied to the newly added claims.

The Examiner asserts that "since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. . . , one skilled in the art clearly would not know how to use the claimed invention." *See* Office Action at page 6. Applicants respectfully disagree. For the reasons discussed above in response to the rejection under 35 U.S.C. § 101, the claimed invention is supported by a specific, substantial and credible asserted utility. The Examiner "should not impose a 35 U.S.C. 112, first paragraph, rejection grounded on a 'lack of utility' basis unless a 35 U.S.C. 101 rejection is proper." M.P.E.P. § 2107 (IV) at 2100-28. Therefore, because the claimed invention complies with the utility requirement of 35 U.S.C. § 101, the rejections under 35 U.S.C. § 112, first paragraph, based on the alleged lack of utility of the claimed invention, should be withdrawn.

B. The Rejection of Claims 1-3, 8-10 and 22 for Enablement

At pages 7-8 of the Office Action, claims 1-3, 8-10 and 22 have been rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter which was not described in the specification in such as way as to "enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims." Office Action at page 7.

Applicant respectfully disagrees with this rejection. However, as indicated above, claims 1-3, 8-10 and 22 have been cancelled without prejudice or disclaimer, thus rendering moot this rejection. Applicants respectfully traverse this rejection, as it may be applied to the newly added claims.

The test for enablement is whether the disclosure when filed contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. M.P.E.P. § 2164.01. The standard applied is whether the experimentation needed to practice the invention is undue. *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). However, "[a] patent need not disclose what is well known in the art." *Id.* Whether the specification is enabling must be analyzed in light of factors such as the state of the prior art and the level of one of ordinary skill. *Id.*; *see also* M.P.E.P. § 2164.01(a).

The Examiner argues that "[t]he claims are drawn to polynucleotides and a method of making peptides which encompass variants and sequences comprising fragments that could vary widely in structure and function. . . . There is no particular activity required." *See* Office Action at page 8. Applicant respectfully points out to the Examiner that new independent claims 31, 46, and 61 and claims dependent thereto are directed to variants or fragments of SEQ ID NO:2 which "modulate[] inhibition of axonal elongation." Therefore, these claims require a "particular activity."

The Examiner further asserts that "there are no required common regions and there is no guidance as to what could be changed and what could not be changed to preserve any common characteristics." Office action at page 8. Applicant respectfully disagrees. First, the specification provides considerable guidance about the type of amino acids changes that could be made without affecting the ability of the claimed polypeptide to modulate inhibition of axonal elongation. Specifically, the specification describes the amino acid residues that make up each of the various NOGO receptor 2 (NgR2) domains and further states that "amino acid residues that are conserved among

family members of the NgR proteins of the present invention . . . are also predicted to be particularly unamenable to alteration. . . . Amino acids that are not conserved or are only semi-conserved among members of the NgR proteins may be readily amenable to alteration. *See* specification at page 57, line 25 through page 58, line 10 and page 57, lines 14-21. Furthermore, the specification teaches that a conservative substitution is recognized in the art as a substitution of one amino acid for another amino acid that has similar properties. In addition, the specification sets out exemplary conservative substitutions in Tables 2-4. Thus, the specification provides clear guidance to the skilled artisan as to what amino acid variations would be tolerated.

In addition, Applicant asserts, as indicated above, that the NgR is composed of multiple leucine rich repeats, the structure of which were well known in the art when the present application was filed. *See Kobe et al.*, TIBS 19: 415-421 (1994) (attached hereto as Exhibit 3). Specifically, this reference provides a detailed analysis of the structure of the leucine rich repeats present in numerous polypeptides, and their contribution to the structural integrity of those polypeptides. Thus, one of skill in the art would know what substitutions, deletions and insertions could be made to the amino acid sequence, but still retain the structural integrity of the leucine rich repeats of NgR.

The specification further describes methods for obtaining variants of the claimed polypeptides including "site-directed mutagenesis and PCR-mediated mutagenesis." The specification further teaches that "conservative amino acid substitutions can be made at one or more amino acid residues predicted to be non-essential. Alternatively, mutations can be introduced randomly along a NgR coding sequence. This can be accomplished, *e.g.*, by saturation mutagenesis." Specification at page 58, lines 24-27. Thus, on the

basis of the specification and the knowledge in the art, one of ordinary skill in the art would know what amino acid substitutions, deletions or insertions could likely be made without altering the function of NgR2, and would know how to make such substitutions.

At that point, one of ordinary skill in the art would easily have been able to test the polypeptides of the invention for the appropriate activity using routine techniques. *See, e.g.,* Huang *et al.*, *Neuron* 24:639-47 (1999). Additionally, in the present specification, Applicant teaches assays that could be routinely used by one of ordinary skill in the art to test whether variants had the required function. For example, binding assays could easily be performed to determine whether a given polypeptide of the invention can modulate inhibition of axonal elongation by binding to a ligand of NgR2. *See* specification at page 69, line 25 through page 76, line 2. Therefore, since the disclosed or otherwise known methods of making and screening the claimed polypeptides may be used to determine, without undue experimentation, whether a given polypeptide encompassed by the claims can be used to inhibit NOGO-receptor-mediated neurite outgrowth inhibition, the enablement requirement is fully satisfied. *In re Wands*, 858 F.2d at 738, 8 USPQ2d at 1404; *Ex parte Mark*, 12 USPQ2d 1904, 1906-07 (B.P.A.I. 1989).

Thus, Applicant respectfully asserts that one of ordinary skill in the art would be able to make and use the invention, as presently claimed, without undue experimentation. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

C. The Rejection of Claims 1-3, 8-10 and 22 for Written Description

At pages 8-9 of the Office Action, claims 1-3, 8-10 and 22 have been rejected under 35 U.S.C. § 112, first paragraph for allegedly “containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.” Office Action at page 8. Briefly, the Examiner contends that the specification provides insufficient descriptive information to show possession of the claimed genus of polynucleotides. Applicant respectfully disagrees with this rejection. However, as indicated above, claims 1-3, 8-10 and 22 have been cancelled without prejudice or disclaimer, thus rendering moot this rejection. Applicants respectfully traverse this rejection, as it may be applied to the newly added claims.

In an analysis of written description under 35 U.S.C. § 112, first paragraph, the Examiner bears the initial burden of presenting a *prima facie* case of unpatentability. This burden is only discharged if the Examiner can present evidence or reasons why one skilled in the art would not reasonably conclude that Applicants possessed the subject matter as of the priority date of the present application. *In re Wertheim*, 541 F.2d 257, 262, 191 U.S.P.Q.2d 90, 96 (C.C.P.A. 1976); M.P.E.P. § 2163.04. In the instant case, Applicant maintains that the Examiner has not met this burden.

The test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor had possession of the claimed invention based on the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); M.P.E.P. § 2163.02. Indeed, as the Federal Circuit has noted, “the issue is whether one of skill in the art could derive the claimed ranges from the patent’s disclosure.” *Union Oil Company of California v. Atlantic*

Richfield Company, 208 F.3d 989, 54 U.S.P.Q. 2d 1227 (Fed. Cir. 2000) (emphasis added).

NgR2 is a member of the NgR family. It was well known in the art that there was a characteristic pattern of sequence conservation in the NgR family, *i.e.*, the NgR family is composed of multiple leucine rich repeats, the structure of which were well known in the art when the present application was filed. *See Kobe et al.*, TIBS 19: 415-421 (1994) (attached hereto as Appendix 3). Given that the skilled artisan would have been familiar with this well known conservation among Nogo receptors and given the teachings of the present application, the skilled artisan could clearly envision the fragments that would retain the structural and/or functional attributes of NgR2. *See* specification at page 46, line 14 through page 58, line 31. Thus, it would be readily apparent to the skilled artisan that the Applicants had "invented what is claimed" *Vas-Cath*, 935 F.2d at 1563. Accordingly, one skilled in the art, enlightened by the teachings of the present application, could readily envision all of the various polynucleotide sequences of the specified polynucleotides.

Applicant asserts that the specification conveys with reasonable clarity that the Applicant was in possession of the claimed invention and that the claims are fully supported by the specification. Moreover, Applicant respectfully asserts that the Examiner has failed to meet the required burden in presenting evidence or reasons why those skilled in the art would not recognize the claimed invention from the disclosure. For all of the above reasons, Applicant respectfully asserts that the present specification provides sufficient written description to convey to one of ordinary skill that Applicant had possession of the full scope of the claimed invention upon filing of the application.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, are respectfully requested.

VIII. Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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| Exhibit 1 | Binding of myelin ligand to rNgR1 and huNgR2, 3 fusion protein |
| Exhibit 2 | huNgR2-(310)Fc promotes neurite outgrowth in a dose dependent manner and to near control at 1 μ M on MAG-Fc |
| Exhibit 3 | Kobe <i>et al.</i> , TIBS 19: 415-421 (1994). |